SPECIAL eBULLETIN

MARCH 2020

MARCH/APRIL 2020 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for March/April 2020. The formularies and pharmaceutical management procedures are updated on a bimonthly basis, and the following changes reflect the decisions made in January 2020 by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Please reference the guide below to navigate this communication:

As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (accessible via NaviNet® or our website). Click the **Pharmacy Program/Formularies** link from the menu on the left.

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Important Drug Safety Updates

Update: Health Professional and Consumer on Recent Recalled Products Due to Detection of Impurities and Potential Risk of Cancer

As part of an ongoing investigation into the voluntary recall of products due to the detection of probable human carcinogen impurities and increased risk of cancer, there was one additional voluntary recall. Health care professionals should be aware that the recalled products pose an unnecessary risk to patients.

Pharmacists and physicians may direct patients to alternative treatment prior to returning to their medications. Physicians should evaluate the risk versus the benefit if treatment is stopped immediately, as stopping treatment immediately without alternative treatment may lead to a higher risk of harm to the patient's health.

The additional products that have been recalled due to the impurities are listed below. Not all products from all the manufacturers are recalled. Patients and physicians should check the FDA website to see if the lot number of their medication has been included in the recall.

Manufacturer	Recalled Drugs	Detected Impurity
Mylan Pharmaceuticals	Nizatidine capsules, USP	N-Nitrosodimethylamine (NDMA)

Gabapentin (Neurontin, Gralise, Horizant) and pregabalin (Lyrica, Lyrica CR): Drug Safety Communication – Warning About Serious Breathing Problems

On December 19, 2019, the FDA announced a warning that serious breathing difficulties may occur in patients using gabapentin (Neurontin, Gralise, Horizant) or pregabalin (Lyrica, Lyrica CR) who have respiratory risk factors. As a result, the FDA requires new warnings about the risk of respiratory depression be added to the prescribing information of the gabapentinoids. The FDA also requires the drug manufacturers to conduct clinical trials to further evaluate their abuse potential, particularly in combination with opioids, because misuse and abuse of these products together is increasing, and co-use may increase the risk of respiratory depression. Health care professionals should start gabapentinoids at the lowest dose and monitor patients for symptoms of respiratory depression and sedation when co-prescribing gabapentinoids with an opioid or other central nervous system depressant. Patients with underlying respiratory disease and elderly patients are also at increased risk and should be managed similarly.

Mirtazapine Tablets by Aurobindo Pharma USA.: Recall – Label Error on Declared Strength

On December 31, 2019, Aurobindo Pharma USA, Inc., voluntarily recalled lot number 03119002A3 of Mirtazapine tablets to the consumer level. The product was recalled due to a label error on declared strength. Bottles labeled as Mirtazapine 7.5 mg may contain 15 mg tablets. Taking a higher dose than expected may increase risk of sedation, agitation, increased reflexes, tremor, sweating, dilated pupils, gastrointestinal distress, nausea, constipation and more.

Lamotrigine Tablets USP, 100mg, 100 Count Bottles by Taro Pharmaceuticals U.S.A., Inc.: Recall – Cross-Contamination

On January 10, 2020, Taro Pharmaceuticals U.S.A., Inc., voluntarily recalled one lot (Lot #331771, expiration date June 2021) of Lamotrigine 100 mg tablets in 100 count bottles. The single lot of this product was found to have been cross-contaminated with a small amount of another drug substance (Enalapril Maleate) used to manufacture another product at the same facility. Enalapril Maleate is associated with risk of birth defects in a developing fetus. Therefore, there is a risk associated with chronic exposure to Enalapril Maleate to impact users, particularly if they are small children or pregnant women.

Belviq, Belviq XR (lorcaserin): Drug Safety Communication –Possible Increased Risk of Cancer

On January 14, 2020, the FDA issued an alert to the public that resulted from a clinical trial assessing safety showing a possible increased risk of cancer with the weight management medications, Belviq and Belviq XR (lorcaserin). Although the cause of the cancer is uncertain, and the FDA cannot conclude that lorcaserin contributes to the cancer risk, the FDA wanted to make the public aware of the potential risk and is continuing to evaluate the clinical trial results. On February 13, 2020, the FDA has requested that the manufacturer of Belviq, Belviq XR (lorcaserin) voluntarily withdraw the weight-loss drug from the U.S. market. Health care professionals should stop prescribing and dispensing lorcaserin to patients. Patients should stop taking lorcaserin and should talk to their health professionals about alternative weight-loss medicines and weight management program.

Clozapine (Clozaril): Drug Safety Communication –Warning of Untreated Constipation Caused by Clozaril (clozapine) Can Lead to Serious Bowel Problems

On January 28, 2020, the FDA strengthened an existing warning that constipation caused by the schizophrenia medicine clozapine (Clozaril, Fazaclo ODT, Versacloz, generics) can, uncommonly, progress to serious bowel complications. This can lead to hospitalization or even death if constipation is not diagnosed and treated quickly. Health care professionals should evaluate bowel function before starting a patient on clozapine and avoid co-prescribing clozapine with other anticholinergic medicines that can cause gastrointestinal hypomotility. Advise patients frequently of the significant risk of constipation, life-threatening bowel issues, and the need to stay hydrated. Question patients about the frequency and quality of their bowel movements throughout treatment, and advise patients to contact a health care professional right away if they have any difficulty with bowel movement or passing stools. Monitor patients for symptoms of potential complications associated with gastrointestinal hypomotility. Consider prophylactic laxative treatment when starting clozapine in patients with a history of constipation or bowel obstruction.

Highmark Formulary Update – March 2020

SECTION I. Highmark Commercial and Healthcare Reform Formularies

A. Changes to the Highmark Comprehensive Formulary and the Highmark Comprehensive Healthcare Reform Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. Please note that the Highmark Comprehensive Closed/Incentive Formulary is a complete subset of the Open Formulary; therefore, all medications added to the Comprehensive Closed/Incentive Formulary are also added to the Open Formulary. These updates are effective on the dates noted throughout this document. For your convenience, you can search the following formularies online:

Highmark Comprehensive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=8103967260)
Highmark Comprehensive Healthcare Reform Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=4906449921)

Highmark is happy to inform you that Table 1 includes products that have been added to the formulary. Adding products to the formulary may mean lower copays or coinsurance rates for members. By adding products to the formulary, Highmark hopes to promote adherence to medication protocols and improve the overall health of our members.

Table 1. Products Added
(All products added to the formulary effective March 12, 2020, unless otherwise noted.)

Brand Name	Generic Name	Comments
Ibrance tablets*	palbociclib	Ibrance is indicated for the treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men; or with fulvestrant in patients with disease progression following endocrine therapy.
Fluzone High-Dose Quadrivalent*	influenza vaccine	Vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine

*Effective date to be determined.
Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Vumerity	diroximel fumarate	Tecfidera, Gilenya
Ziextenzo	pegfilgrastim-bmez	Neulasta syringe, Neupogen
Absorica LD	isotretinoin	Zenatane, Myorisan, Amnesteem

Brand Name	Generic Name	Preferred Alternatives
Abrilada*	adalimumab-afzb	Humira
Xcopri*	cenobamat	levetiracetam tablets, gabapentin tablets, gabapentin capsules
Exservan oral film*	riluzole	riluzole oral tablet
Arazlo 0.045% lotion*	tazarotene	tretinoin topical gel, tretinoin topical cream
Conjupri*	levamlodipine	amlodipine tablet, felodipine extended-release tablet, nifedipine extended-release tablet
Dayvigo*	lemborexant	zolpidem oral tablet, temazepam
Caplyta	lumateperone	olanzapine tablet, quetiapine fumarate tablet, risperidone tablet
Ubrelvy	ubrogepant	sumatriptan succinate tablet, rizatriptan tablet, zolmitriptan tablet
Ayvakit	avapritinib	imatinib oral tablet
Valtoco nasal spray	diazepam	diazepam kit
Talicia	omeprazole/amoxicillin/rifabutin	lansoprazole-amoxicillin-clarithromycin
Brukinsa	zanubrutinib	Provider discretion
Oxbryta	voxelotor	Provider discretion
Ervebo*	Ebola Zaire vaccine	Provider discretion

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
Physicians may request coverage of these products using the Prescription Drug Medication Request Form, which can be accessed online in Highmark's Provider Resource Center. Under **Provider Forms, select **Miscellaneous Forms**, and select the form titled **Request for Non-Formulary Drug Coverage**.

Table 3. Additions to the Specialty Tier Copay Option

Note: The specialty tier does not apply to Highmark Delaware Healthcare Reform members; see Highmark Delaware's online Provider Resource Center and access the **Pharmacy Program/Formularies** link for details on the formularies and formulary options that apply to Highmark Delaware Healthcare Reform members.

(Effective upon completion of internal review and implementation unless otherwise noted.)

Brand Name	Generic Name
Brukinsa	zanubrutinib
Abrilada	adalimumab-afzb
Exservan oral film	riluzole
Oxbryta	voxelotor
Ayvakit	avapritinib
Vumerity	diroximel fumarate
Ziextenzo	pegfilgrastim-bmez

B. Changes to the Highmark Progressive Formulary and the Highmark Healthcare Reform Progressive Formulary

Note: The Progressive Formulary does not apply to Highmark Delaware members; see Highmark Delaware's online Provider Resource Center and access the **Pharmacy Program/Formularies** link for details on the formularies and formulary options that apply to Highmark Delaware members. For your convenience, you may search the following formularies online:

Highmark Progressive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=1176922773)
Highmark Healthcare Reform Progressive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=4909431197)

Table 1. Formulary Updates (All products added to the formulary effective March 12, 2020, unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below are preferred products			
Fluzone High-Dose Quadrivalent*	influenza vaccine	2 – Preferred brand	Vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine
Ibrance tablets*	palbociclib	3 – Preferred specialty	Ibrance is indicated for the treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men; or with fulvestrant in patients with disease progression following endocrine therapy.
Items listed below are non-preferred products			
Absorica LD	isotretinoin	3 – Non-preferred brand	Zenatane, Myorisan, isotretinoin capsule
Xcopri*	cenobamate	3 – Non-preferred brand	levetiracetam tablets, gabapentin tablets, gabapentin capsules
Arazlo 0.045% lotion*	tazarotene	3 – Non-preferred brand	tretinoin topical gel, tretinoin topical cream
Conjupri*	levamlodipine	3 – Non-preferred brand	amlodipine tablet, felodipine extended-release tablet, nifedipine extended-release tablet
Dayvigo*	lemborexant	3 – Non-preferred brand	zolpidem oral tablet, temazepam

Caplyta	lumateperone	3 – Non-preferred brand	olanzapine tablet, quetiapine fumarate tablet, risperidone tablet
Ubrelvy	ubrogepant	3 – Non-preferred brand	sumatriptan succinate tablet, rizatriptan tablet, zolmitriptan tablet
Valtoco nasal spray	diazepam	3 – Non-preferred brand	diazepam kit
Vumerity	diroximel fumarate	4 – Non-preferred specialty	Tecfidera, Gilenya
Ziextenzo	pegfilgrastim-bmez	4 – Non-preferred specialty	Neulasta syringe, Neupogen
Abrilada*	adalimumab-afzb	4 – Non-preferred specialty	Humira
Exservan oral film*	riluzole	4 – Non-preferred specialty	riluzole oral tablet
Ayvakit	avapritinib	4 – Non-preferred specialty	imatinib oral tablet
Talicia	omeprazole/amoxicillin/rifabutin	3 – Non-preferred brand	lansoprazole-amoxicillin-clarithromycin†
Ervebo*	Ebola Zaire vaccine	3 – Non-preferred brand	Provider discretion
Brukinsa	zanubrutinib	4 – Non-preferred specialty	Provider discretion
Oxbryta	voxelotor	4 – Non-preferred specialty	Provider discretion

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
† *Preferred product only for Commercial Progressive Formulary*
Tier 1: Preferred generic drugs; **Tier 2:** Preferred brand drugs; **Tier 3:** Non-preferred generic drugs, non-preferred brand drugs, preferred specialty drugs; **Tier 4:** Non-preferred specialty drugs.

C. Changes to the Highmark Healthcare Reform Essential Formulary

The Essential Formulary is a closed formulary for select Healthcare Reform (HCR) Individual plans. A list of drugs included on the Essential Formulary, listed by therapeutic class, is available at https://client.formularynavigator.com/Search.aspx?siteCode=6571849149.

Table 1. Formulary Updates
(All formulary changes effective March 12, 2020, unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Fluzone High-Dose Quadrivalent*	influenza vaccine	3	Vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine
Ibrance tablets*	palbociclib	4	Ibrance is indicated for the treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
			combination with an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men; or with fulvestrant in patients with disease progression following endocrine therapy.
Items listed below were not added to the formulary			
Vumerity	diroximel fumarate	NF	Aubagio, Gilenya
Ziextenzo	pegfilgrastim-bmez	NF	Zarxio
Absorica LD	isotretinoin	NF	Zentane, Myorisan, Amnesteem
Brukinsa	zanubrutinib	NF	Imbruvica
Abrilada*	adalimumab-afzb	NF	Humira
Xcopri*	cenobamate	NF	levetiracetam tablets, gabapentin tablets, gabapentin capsule
Exservan oral film*	riluzole	NF	riluzole oral tablet
Arazlo 0.045% lotion*	tazarotene	NF	tretinoin topical gel, tretinoin topical cream
Conjupri*	levamlodipine	NF	amlodipine tablet, felodipine extended-release tablet, nifedipine extended-release tablet
Dayvigo*	lemborexant	NF	zolpidem oral tablet, temazepam
Caplyta	lumateperone	NF	olanzapine tablet, quetiapine fumarate tablet, risperidone tablet
Ubrelvy	ubrogepant	NF	sumatriptan succinate tablet, rizatriptan tablet, zolmitriptan tablet
Ayvakit	avapritinib	NF	imatinib oral tablet
Valtoco nasal spray	diazepam	NF	diazepam kit
Talicia	omeprazole/amoxicillin/rifabutin	NF	Provider discretion
Oxbryta	voxelotor	NF	Provider discretion
Ervebo*	Ebola Zaire vaccine	NF	Provider discretion

Formulary options: Tier 1, Tier 2, Tier 3, Tier 4, Non-formulary (NF).
*Effective date to be determined.

D. Changes to the Highmark Core Formulary

The Core Formulary is a closed formulary for select Commercial plans. A list of drugs included on the Core Formulary, listed by therapeutic class, is available at https://client.formularynavigator.com/Search.aspx?siteCode=0874170847.

Table 1. Formulary Updates
(All formulary changes effective March 12, 2020, unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Fluzone High-Dose Quadrivalent*	influenza vaccine	3	Vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine
Ibrance tablets*	palbociclib	4	Ibrance is indicated for the treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men; or with fulvestrant in patients with disease progression following endocrine therapy.
Items listed below were not added to the formulary			
Vumerity	diroximel fumarate	NF	Aubagio, Gilenya, Tecfidera
Ziextenzo	pegfilgrastim-bmez	NF	Nivestym
Absorica LD	isotretinoin	NF	Zentane, Myorisan, Amnesteem
Brukinsa	zanubrutinib	NF	Imbruvica, Calquence
Abrilada*	adalimumab-afzb	NF	Humira
Xcopri*	cenobamate	NF	levetiracetam tablets, gabapentin tablets, gabapentin capsule
Exservan oral film*	riluzole	NF	riluzole oral tablet
Arazlo 0.045% lotion*	tazarotene	NF	tretinoin topical gel, tretinoin topical cream
Conjupri*	levamlodipine	NF	amlodipine tablet, felodipine extended-release tablet, nifedipine extended-release tablet
Dayvigo*	lemborexant	NF	zolpidem oral tablet, temazepam
Caplyta	lumateperone	NF	olanzapine tablet, quetiapine fumarate tablet, risperidone tablet
Ubrelvy	ubrogepant	NF	sumatriptan succinate tablet, rizatriptan tablet, zolmitriptan tablet
Ayvakit	avapritinib	NF	imatinib oral tablet
Valtoco nasal spray	diazepam	NF	diazepam kit
Talicia	omeprazole/amoxicillin/rifabutin	NF	Provider discretion

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Oxbryta	voxelotor	NF	Provider discretion
Ervebo*	Ebola Zaire vaccine	NF	Provider discretion

Formulary options: Tier 1, Tier 2, Tier 3, Tier 4, Non-formulary (NF).
*Effective date to be determined.

E. Changes to the Highmark National Select Formulary

The National Select Formulary is an incentive formulary with a non-formulary drug list to manage products in therapeutic categories for which preferred alternatives are available. The National Select Formulary is available for select Commercial self-funded (ASO) plans. A list of drugs included on the National Select Formulary, listed by therapeutic class, is available at https://client.formularynavigator.com/Search.aspx?siteCode=3442182690.

Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (preferred)			
Items listed below were added to the formulary (non-preferred)			
Vumerity*	diroximel fumarate	3	Tecfidera, Gilenya, Mayzent
Exservan oral film*	riluzole	3	riluzole oral tablet
Talicia*	(omeprazole/amoxicillin/ rifrabutin)	3	lansoprazole-amoxicillin-clarithromycin
Ziextenzo*	pegfilgrastim-bmez	3	Neulasta syringe, Udenyca
Brukinsa	zanubrutinib	3	Imbruvica
Abrilada*	adalimumab-afzb	3	Humira
Xcopri*	cenobamate	3	levetiracetam tablets, gabapentin tablets, gabapentin capsules
Arazlo 0.045% lotion*	tazarotene	3	tretinoin topical gel, tretinoin topical cream
Conjupri*	levamlodipine	3	amlodipine tablet, felodipine extended-release tablet, nifedipine extended-release
Ervebo*	Ebola Zaire vaccine	3	Provider discretion
Dayvigo*	lemborexant	3	zolpidem oral tablet, temazepam
Caplyta*	lumateperone	3	olanzapine tablet, quetiapine fumarate tablet, risperidone tablet
Ubrelvy*	ubrogepant	3	sumatriptan succinate tablet, rizatriptan tablet, zolmitriptan tablet
Ayvakit*	avapritinib	3	imatinib oral tablet
Valtoco nasal spray*	diazepam	3	diazepam kit
Absorica LD	isotretinoin	3	Amnesteem, Claravis, Myorisan, Zenatane
Ibrance tablets*	palbociclib	3	Ibrance capsules

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Fluzone High-Dose Quadrivalent*	influenza vaccine	3	Provider discretion
Items listed below were not added to the formulary			
Oxbryta	voxelotor	NF	hydroxyurea, Droxia

Formulary options: Tier 1, Tier 2, Tier 3, Non-formulary (NF).
*Effective date and final formulary position to be determined.

Table 2. Additions to the Specialty Tier Copay Option
(Effective upon completion of internal review and implementation unless otherwise noted.)

Brand Name	Generic Name
Brukinsa	zanubrutinib
Abrilada	adalimumab-afzb
Exservan oral film	riluzole
Oxbryta	voxelotor
Ayvakit	avapritinib
Vumerity	diroximel fumarate
Ziextenzo	pegfilgrastim-bmez

F. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Adcirca and Alyq (tadalafil) – Healthcare Reform Essential Formulary	2/13/2020	Policy revised for pulmonary hypertension agents by removing reasoning why member is using the agent as diagnosis is already required. Applies to all targeted agents.
Conjupri (levamlodipine) – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use in members with a diagnosis of hypertension who have experienced therapeutic failure, contraindication, or intolerance to two of the following: amlodipine, felodipine, nifedipine extended-release.
Pulmonary Hypertension – Commercial and Healthcare Reform	TBD	Policy revised for pulmonary hypertension agents to clarify that New York Heart Association (NYHA) or World Health Organization (WHO) functional class symptoms are from baseline and removal of reasoning why member is using the agent as diagnosis is already required. Applies to all targeted agents.
Impoyz (clobetasol propionate) – Commercial and Healthcare Reform	2/25/2020	Policy terminated. Impoyz is captured in topical corticosteroid policies for Commercial and Healthcare Reform.
Oral Isotretinoin Therapy – Commercial	Best Date	Policy revised for Oral Isotretinoin Therapy that member is 12 years of age or older. Addition of Absorica LD

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		(isotretinoin) to policy with requirements of age 12 years or older, diagnosis of severe nodular acne, failure, intolerance or contraindication to one generic oral antibiotic, two different topical acne agents or one combination product, and failure or intolerance to one of the following: Amnesteem, Claravis, Myorisan, Zenatane (isotretinoin). Reauthorization criteria of an 8 week waiting period after the initial course and persistent or recurring severe acne following the initial course.
Solaraze (diclofenac sodium 3%) gel and Carac (fluorouracil 0.5%) cream – Commercial and Healthcare Reform	2/13/2020	Policy revised for Solaraze (diclofenac 3%) to specify that members step through fluorouracil 5% solution or cream and for Carac (fluorouracil 0.5%) to specify that members step through brand or generic fluorouracil 5% topical cream. Additionally, if a brand product is requested, the member is required to step through the generic equivalent.
Korlym (mifepristone) – Commercial and Healthcare Reform	2/13/2020	Policy revised to allow for Korlym (mifepristone) use in members with glucose intolerance. Policy revised to clarify that Korlym may be used in addition to diabetes therapy or lifestyle modification.
Myalept (metreleptin) – Commercial and Healthcare Reform	2/13/2020	Policy revised to remove requirement that the member needs to be optimized on diabetic or hypertriglyceridemia medications.
Testosterone (Androgens) – Commercial and Healthcare Reform	2/13/2020	Policy revised to change the minimum age for gender dysphoria from 16 years to 14 years and to change the goal of testosterone therapy to masculinization.
Market Watch Programs – PA, WV, and DE	Best Date	Policy revised to include Conjupri (levamlodipine) as a target for the High Cost Low Value Program with therapeutic alternatives of amlodipine, felodipine, and nifedipine extended-release.
West Virginia - Step Therapy/Prior Authorization Override Exception – Commercial and Healthcare Reform	1/1/2020	Policy revised to clarify re-authorization criteria for prior authorization medication requests after initial 3 month approval period; various administrative changes.
H. Pylori Treatments- Commercial and Healthcare Reform	TBD	New policy created to ensure appropriate use of H. pylori treatment Pylera (bismuth/metronid/tetracycline), in patients who have had failure to first line treatments.
Talicia (omeprazole/amoxicillin/rifabutin) – Commercial and Healthcare Reform	3/3/2020	New policy created to ensure appropriate use of H. pylori treatment, Talicia (omeprazole/amoxicillin/rifabutin), in patients who have had failure to first line treatments
Chelating Agents – Commercial and Healthcare Reform	4/1/2020	Policy revised for chelating agents to specify that step therapy through generic deferasirox must be the generic of Exjade (deferasirox).

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Hemlibra (emicizumab) – Commercial and Healthcare Reform	2/13/2020	Policy revised for Hemlibra (emicizumab) to include list of 11 reasons on why routine prophylaxis would be needed in which member only needs to meet one. Reauthorization criteria expanded to require positive clinical response and documentation of bleeding episodes during Hemlibra therapy include date of bleed, type of bleed, and name and number of agents used to reverse bleed. Clarified quantity limit override table. Authorization duration for loading dose is 4 weeks.
Oxbryta (voxelotor) – Commercial and Healthcare Reform	2/18/2020	New policy created for Oxbryta (voxelotor) to require member is 12 years of age or older with sickle cell disease (SCD). Clinical documentation that the member's hemoglobin level is between ≥ 5.5 and ≤ 10.5 g/dL. Reauthorization criteria that the member has experienced a positive response. Authorization duration 12 months.
Adalimumab BIOSIMILARS – Commercial and Healthcare Reform	TBD	Policy revised to include Abrilada (adalimumab-afzb). Policy revised to include exception criteria for members that may require initial biologic therapy for juvenile idiopathic arthritis and to step through two immunosuppressants to one corticosteroid for severe ulcerative colitis. The policy split out the recommended age group for each diagnosis.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	2/5/2020	Policy revised to include Stelara (ustekinumab) and Xeljanz XR (tofacitinib XR) as non-preferred agents for ulcerative colitis. Policy revised to ensure that members try three preferred agents prior to receiving Taltz (ixekizumab) for plaque psoriasis.
Etanercept BIOSIMILARS – Commercial and Healthcare Reform	TBD	Policy revised to include Eticovo (etanercept-ykro) and expanded indications of psoriatic arthritis and plaque psoriasis for Erelzi (etanercept-szzs). Policy revised to include exception criteria for members that may require initial biologic therapy for juvenile idiopathic arthritis. The policy split out the recommended age group for each diagnosis.
Interferons – Commercial and Healthcare Reform	2/13/2020	Policy revised to include all targeted Interferon products, requiring an FDA approved indication and appropriate age for use.
Sublingual Immunotherapy – Commercial and Healthcare Reform	2/13/2020	Policy revised to extend the indication for Oralair (sweet vernal, orchard, perennial rye, timothy and Kentucky blue grass mixed pollens allergens extract) for use in members five to nine years of age.
Hepatitis C Oral Agents – Commercial, Healthcare Reform, Commercial Core and National Select Formulary	2/13/2020	Policy revised to align with the most recent American Association for the Study of Liver Diseases/Infection Diseases Society of America (AASLD/IDSA) guidelines, ensure prescriber educates the member on the adverse effects of alcohol or intravenous (IV) drug abuse and the prescriber attests a referral to substance abuse treatment

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		if the member has alcohol use disorder, IV drug abuser or had a history of substance abuse within the past 6 months.
Intra-articular hyaluronan – Commercial and Healthcare Reform	2/23/2020	Policy terminated.
Savella (milnacipran) – Commercial and Healthcare Reform	2/13/2020	Policy revised for Savella (milnacipran) that member is 18 years of age or older. Defined tried and failed tricyclic agent as amitriptyline and removed selective serotonin reuptake inhibitors (SSRIs). Reauthorization criteria attesting positive response. Authorization duration changed to 12 months.
Apokyn (apomorphine) – Commercial and Healthcare Reform	2/13/2020	Policy revised to require therapeutic failure, contraindication, or intolerance to pramipexole or pramipexole ER; ropinirole or ropinirole ER; and either entacapone, rasagiline, or selegiline.
Austedo (deutetrabenazine) – Commercial and Healthcare Reform	2/13/2020	Policy revised for Austedo (deutetrabenazine) to remove criteria requiring prescription from a neurologist or psychiatrist; to edit criterion for quantity limit above 48 mg/day when provider provides clinical rationale; to add criterion for approval in adults (18 years or older) for tardive dyskinesia and Huntingdon's disease; and to revise criteria for prescriber attestation that the member is not actively suicidal.
Exservan and Tiglutik (riluzole) – Commercial and Healthcare Reform	Best Date	Policy revised to include the newly FDA-approved Exservan (oral-film formulation of riluzole) for members with a diagnosis of amyotrophic lateral sclerosis (ALS) who have an inability to swallow tablets.
Horizant (gabapentin enacarbil) – Commercial and Healthcare Reform	2/13/2020	Policy revised to add reauthorization criteria that the prescriber attests to positive clinical response to therapy for reauthorization of Horizant (gabapentin enacarbil).
Nourianz (istradefylline) – Commercial and Healthcare Reform	2/13/2020	Policy revised to require therapeutic failure, contraindication, or intolerance to 3 of the following agents: selegiline, rasagiline, pramipexole or pramipexole ER, ropinirole or ropinirole ER, or entacapone.
Provigil (modafinil) & Nuvigil (armodafinil) – Commercial and Healthcare Reform (Delaware Only)	2/13/2020	Policy revised to include age criteria and baseline documentation of excessive daytime sleepiness (EDS) via the Epworth Sleepiness Scale or Maintenance of Wakefulness test and use of the above criteria to demonstrate the member has a decrease in EDS for reauthorization.
Tecfidera (dimethyl fumarate) and Vumerity (diroximel fumarate) – Commercial and Healthcare Reform	2/18/2020	Policy revised to include Vumerity (diroximel fumarate) with requirements of age of 18 years of age or older and diagnosis of a relapsing form of multiple sclerosis. Addition of reauthorization criteria requiring disease improvement, stability, or delayed disease progression.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Xadago (safinamide) – Commercial and Healthcare Reform	2/13/2020	Policy revised to ensure members have experienced therapeutic failure, contraindication, or intolerance to either entacapone; ropinirole or ropinirole ER; pramipexole or pramipexole ER; in addition to rasagiline and selegiline for approval of Xadago (safinamide).
Xcopri (cenobamate) – Commercial and Healthcare Reform	Best Date	New policy created for Xcopri (cenobamate) to require age of 18 years or older, diagnosis of partial-onset seizures, and trial of one other anti-epileptic drug. Reauthorization requiring prescriber attestation that the member has experienced positive clinical response to therapy.
Xenazine (tetrabenazine) – Commercial and Healthcare Reform	2/13/2020	Policy revised for Xenazine (tetrabenazine) to remove criteria requiring prescription from a neurologist.
Afinitor (everolimus) – Commercial and Healthcare Reform	4/1/2020	Policy revised to step through generic everolimus tablets for Afinitor (everolimus); and for Afinitor Disperz (everolimus) to step through generic everolimus tablets for subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis.
Androgen Receptor Inhibitors – Commercial and Healthcare Reform	2/13/2020	Policy revised to include expanded FDA-approved indication for Xtandi (enzalutamide) in metastatic castration-sensitive prostate cancer.
Bruton's Tyrosine Kinase Inhibitors – Commercial and Healthcare Reform	2/19/2020	Policy revised to add criteria for FDA-approved Brukinsa (zanubrutinib) in adults with mantle cell lymphoma who have received at least one prior therapy; and for the FDA-approved expanded indication for Calquence (acalabrutinib) in adults with chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL).
Mozobil (plerixafor) – Commercial and Healthcare Reform	2/13/2020	Policy revised for Mozobil (plerixafor) to add reauthorization criteria for disease improvement or delayed disease progression.
PARP Kinase Inhibitors – Commercial and Healthcare Reform	2/12/2020	Policy revised to provide expanded FDA-approved indication criteria for Lynparza (olaparib) in pancreatic adenocarcinoma.
PDGFR Tyrosine Kinase Inhibitors – Commercial and Healthcare Reform	3/3/2020	New policy created for Ayvakit (avapritinib) to ensure members are 18 years of age or older with a diagnosis of unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation.
Venclexta (venetoclax) – Commercial and Healthcare Reform	2/12/2020	Policy revised to add criteria for the member to be 18 years of age or older for Venclexta (venetoclax) with a diagnosis of CLL or SLL, based on FDA-approved indication.
Interleukin (IL)-5 Antagonists – Commercial and Healthcare Reform	2/12/2020	Policy revised to add quantity limit for initial induction dose.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Ofev (nintedanib) and Esbriet (pirfenidone) – Commercial and Healthcare Reform	2/12/2020	Policy revised to expand prescriber restriction to rheumatologists, that the member has documentation of a high resolution CT scan demonstrating ≥10% pulmonary fibrosis and removed cyclophosphamide step.

*For Commercial and Healthcare Reform policies, an exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.
**All effective dates are tentative and subject to delay pending internal review or approval.

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Brand Statins – Select Commercial Plans	2/12/2020	Policy revised to brand statins to add reauthorization criteria attesting positive clinical response. Changed authorization duration from lifetime to 12 months.
Doxepin 5% Cream – Commercial	2/12/2020	Policy revised for doxepin 5% cream to change authorization duration from 3 months to 1 month.
Eucrisa (crisaborole) – Commercial	TBD	Policy revised to include a step through either generic topical tacrolimus or pimecrolimus.
Oral Isotretinoin Therapy – Healthcare Reform	Best Date	Policy revised to add Absorica LD (isotretinoin) to policy with requirements of age 12 years or older, diagnosis of severe nodular acne, failure, intolerance or contraindication to one generic oral antibiotic, two different topical acne agents or one combination product, and failure or intolerance to one of the following: Amnesteem, Claravis, Myorisan, Zenatane (isotretinoin). Reauthorization criteria of an 8-week waiting period after the initial course and persistent or recurring severe acne following the initial course.
Tazarotene Product – Commercial and Healthcare Reform	Best Date	New policy created for Arazlo (tazarotene) to require diagnosis of acne vulgaris and therapeutic failure, contraindication, or intolerance to two topical acne products (adapalene, clindamycin, erythromycin, tretinoin, or sulfacetamide).
Tazarotene Products – Commercial and Healthcare Reform	TBD	Policy revised to include Tazorac (tazarotene) to require diagnosis of acne vulgaris and therapeutic failure, contraindication, or intolerance to two topical acne products (adapalene, clindamycin, erythromycin, tretinoin, or sulfacetamide) or require diagnosis of plaque psoriasis and therapeutic failure, contraindication, or intolerance to one topical corticosteroid.
Vanos (fluocinonide) – Commercial and Healthcare Reform	2/25/2020	Policy terminated. Vanos is captured in topical corticosteroid policies for Commercial and Healthcare Reform.
Topical Psoriasis Products – Commercial	TBD	Policy revised to include Sorilux (calcipotriene) for members with a diagnosis of plaque psoriasis that have experienced therapeutic failure, contraindication, or intolerance to a prescription topical steroid and generic calcipotriene.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Additional Antibiotic Quantities – Commercial and Healthcare Reform	Best Date	Policy revised to include Xenleta (lefamulin acetate).
Extended Release Opioid Management – Commercial and Healthcare Reform	TBD	Policy revised to remove Embeda (morphine sulfate/naltrexone), brand name Exalgo (hydromorphone HCL) and Avinza. Added Arymo ER (morphine sulfate), Butrans (buprenorphine patches) and Belbuca (buprenorphone HCL). For additions, added information in background as well as quantity limit section. Also, administrative changes.
Immediate-Release Opioid Management – Commercial and Healthcare Reform	TBD	Policy revised to remove Roxybond (oxycodone HCL) and add Ultram (tramadol). Tramadol information also added to background as well as quantity limit section. Also, administrative changes.
Naproxen, Fenoprofen, Relafen DS and Ketoprofen 25 mg – Commercial and Healthcare Reform	TBD	Policy revised to include criteria necessary for coverage of ketoprofen: appropriate diagnosis as well as three formulary prescription or over-the-counter nonsteroidal anti-inflammatory drugs (OTC NSAIDs).
Acute Migraine Therapies – Commercial and Healthcare Reform	2/12/2020	Policy revised to include addition of calcitonin gene-related peptide (CGRP) inhibitors to list of prophylactic migraine medications member can be currently receiving.
Acute Migraine Therapies – Commercial and Healthcare Reform	Best Date	Policy revised to include Ubrelvy (ubrogepant).
Azilect (rasagiline) – Commercial	TBD	Policy revised to require therapeutic failure, contraindication, or intolerance to generic rasagiline if Azilect (rasagiline) is requested. Policy revised to require therapeutic failure, contraindication, or intolerance to one of the following: ropinirole or ropinirole ER; pramipexole or pramipexole ER; or entacapone.
Azilect (rasagiline) – Healthcare Reform	TBD	Policy revised to require therapeutic failure, contraindication, or intolerance to generic rasagiline if Azilect (rasagiline) is requested. Policy revised to require therapeutic failure, contraindication, or intolerance to one of the following: ropinirole or ropinirole ER; pramipexole or pramipexole ER; or entacapone.
Hypnotic Medications – Healthcare Reform	Best Date	Terminated policy and rule. Targeted products are captured in Insomnia Medications policy for Healthcare Reform.
Insomnia Medications – Commercial and Healthcare Reform	Best Date	Policy revised to include Dayvigo (lemborexant) to require diagnosis of insomnia characterized by difficulty with sleep onset and/or sleep maintenance and therapeutic failure, contraindication, or intolerance to two of the following: zolpidem, zolpidem ER, eszopiclone, or zaleplon. Addition of reauthorization criteria requiring attestation that the member has experienced positive clinical response to therapy.
Intranasal Benzodiazepines – Commercial and Healthcare Reform	Best Date	Policy revised to add Valtoco (diazepam) as a targeted drug product for members 6 years of age and older with a diagnosis of acute repetitive seizures or cluster seizures who have experienced therapeutic failure or intolerance to Diastat (rectal diazepam).

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Non-Stimulant Treatment of ADHD/ADD – Commercial and Healthcare Reform	2/12/2020	Policy revised to remove specific contraindications from approval criteria and move to background.
Chemotherapy Induced Nausea and Vomiting (CINV) – Commercial	TBD	Policy revised to provide updated FDA-approved indication criteria for Emend (aprepitant) capsules and oral suspension; Akynzeo (netupitant/palonosetron); Varubi (rolapitant); Zuplenz (ondansetron) film; and Sancuso (granisetron) transdermal patch.
Vyzulta (latanoprostene bunod) – Commercial and Healthcare Reform	2/19/2020	Policy revised to include ophthalmic cholinergic agents as an option for patients to step through.
Atypical Antipsychotics – Commercial	2/12/2020	Policy revised to clarify criteria requiring the use of two different antidepressants (AD) before an antipsychotic (AP) is approved for adjuvant treatment in major depressive disorder (MDD).
Atypical Antipsychotics – Commercial and Healthcare Reform	Best Date	Policy revised to add Caplyta (lumateperone) to ensure appropriate use in adult members with schizophrenia. For Commercial and Healthcare Reform, members must experience therapeutic failure, contraindication, or intolerance to generic quetiapine ER or generic aripiprazole.
Venlafaxine ER – Commercial and Healthcare Reform	TBD	New policy to require use of preferred venlafaxine ER products prior to the use of non-preferred products. J-336, another extended release venlafaxine policy is to be terminated and criteria within will be consolidated in this policy.
budesonide/formoterol fumarate dihydrate – Commercial and Healthcare Reform	TBD	New policy created to step members through brand Symbicort who are requesting the Symbicort authorized generic (budesonide/formoterol fumarate).
Overactive Bladder – Commercial and Healthcare Reform	TBD	New policy created for Enablex (darifenacin), Gelnique (oxybutynin), Toviaz (fesoterodine) and Vesicare (solifenacin) to require therapeutic failure of generic oxybutynin and one of the following agents: darifenacin, solifenacin, trospium.

*For Commercial and Healthcare Reform policies, an exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.
All effective dates are tentative and subject to delay pending internal review or approval.
Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria.

3. Quantity Level Limit (QLL) Programs*
(Effective immediately upon completion of internal review and implementation, unless otherwise noted.)

Table 1. Quantity Level Limits – Quantity per Duration for Commercial and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Abrilada (adalimumab-afzb)*	2 syringes or pens per 28 days	6 syringes or pens per 84 days
Eucrisa (crisaborole)*	1 tube (100 g) per 28 days	3 tubes (300 g) per 84 days
Exservan (riluzole) oral film*	1 carton (60 oral film pouches) per 28 days	3 cartons (180 oral film pouches) per 84 days
Ibrance (palbociclib) tablets*	21 tablets per 21 days	63 tablets per 63 days
Ubrelvy (ubrogepant)	16 tablets per 30 days	48 tablets per 90 days
Xenleta (lefamulin)	10 tablets per 180 days	10 tablets per 180 days
Talicia (omeprazole/amoxicillin/rifabutin)	168 capsules per 365 days	168 capsules per 365 days
Fluzone High-Dose Quadrivalent (influenza vaccine)*	1 dose per 180 days	1 dose per 180 days
Ultram (tramadol)*	240 tablets per 30 days	720 tablets per 90 days

*Effective date to be determined.

Table 2. Quantity Level Limits – Quantity per Dispensing Event – Commercial and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Valtoco (diazepam) nasal spray	2 cartons (4 bottles) per dispensing event	2 cartons (4 bottles) per dispensing event

Quantity per dispensing event limits the quantity of medication that can be dispensed per each fill. If the submitted day supply on a claim is 34 days or less, the retail limit will apply. If the submitted day supply on a claim is greater than 34 days, the mail limit will apply.

Table 3. Maximum Daily Quantity Limits – Commercial and Healthcare Reform Plans

Drug Name	Daily Limit
Ayvakit (avapritinib)	1 tablet per day
Bonjesta (doxylamine/pyridoxine)	2 tablets per day
Brukinsa (zanubrutinib)	4 capsules per day
Caplyta (lumateperone)	1 tablet per day
Conjupri (levamlodipine)*	1 tablet per day
Dayvigo (lemborexant)*	1 tablet per day
Diclegis (doxylamine/pyridoxine)	4 tablets per day
Oxbryta (voxelotor)	3 capsules per day
Samsca (tolvaptan) 15 mg*	1 tablet per day
Samsca (tolvaptan) 30 mg*	2 tablets per day
Sympazan (clobazam)	2 films per day

Drug Name	Daily Limit
Vascepa (icosapent ethyl) 0.5 gram	8 capsules per day
Vascepa (icosapent ethyl) 1 gram	4 capsules per day
Vumerity (diroximel fumarate)	4 capsules per day
Xeljanz XR (tofacitinib) 22 mg	1 tablet per day

*Effective date to be determined.
Members can receive up to the maximum day supply according to their benefits, but the daily limit must not be exceeded for each individual day.

Requests for coverage of select medications exceeding the defined quantity level limits may be submitted for clinical review. Maximum-day supply on certain medications may vary depending on member's benefit design.

SECTION II. Highmark Medicare Part D Formularies

A. Changes to the Highmark Medicare Part D 5-Tier Incentive Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. For your convenience, you can search the Highmark Medicare Part D Formularies online at:

Performance Formulary*:* https://client.formularynavigator.com/Search.aspx?siteCode=1349658900
Venture Formulary: https://client.formularynavigator.com/Search.aspx?siteCode=1347236614
Incentive Formulary*:* https://client.formularynavigator.com/Search.aspx?siteCode=1344627998

Table 1. Preferred Products*
(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Comments
Ervebo	Ebola Zaire vaccine	Provider discretion

Table 2. Non-Preferred Products
(Effective immediately pending Centers for Medicare and Medicaid Services (CMS) approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Preferred Alternatives
Absorica LD	isotretinoin	Amnesteem, Claravis, Myorisan
Xcopri	cenobamate	Levetiracetam tablets, Gabapentin tablets, Gabapentin capsules
Arazlo 0.045% lotion	tazarotene	tretinoin topical gel, tretinoin topical cream
Conjupri	levamlodipine	amlodipine tablet, felodipine extended-release tablet, nifedipine extended-release tablet
Dayvigo	lemborexant	zolpidem oral tablet, ramelteon, temazepam
Ubrelvy	ubrogepant	sumatriptan succinate tablet, zolmitriptan tablet, rizatriptan tablet
Valtoco nasal spray	diazepam	diazepam kit

B. Changes to the Highmark Medicare Part D 5-Tier Closed Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. For your convenience, you can search the Highmark Medicare Part D Formularies online at:

Performance Formulary*:* https://client.formularynavigator.com/Search.aspx?siteCode=1349658900
Venture Formulary: https://client.formularynavigator.com/Search.aspx?siteCode=1347236614
Incentive Formulary: https://client.formularynavigator.com/Search.aspx?siteCode=1344627998

Table 1. Preferred Products

(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Comments
Ervebo	Ebola Zaire vaccine	Provider discretion

Table 2. Non-Preferred Products

(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Preferred Alternatives
Xcopri	cenobamate	Levetiracetam tablets, Gabapentin tablets, Gabapentin capsules
Arazlo 0.045% lotion	tazarotene	tretinoin topical gel, tretinoin topical cream
Ubrelvy	ubrogepant	sumatriptan succinate tablet, zolmitriptan tablet, rizatriptan tablet
Valtoco nasal spray	diazepam	diazepam kit

Table 3. Products Not Added*

(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Preferred Alternatives
Absorica LD	isotretinoin	Amnesteem, Myorisan, Isotretinoin capsule
Abrilada	adalimumab-afzb	Humira
Conjupri	levamlodipine	amlodipine tablet, felodipine extended-release tablet, nifedipine extended-release tablet
Dayvigo	lemborexant	zolpidem oral tablet, ramelteon, temazepam

*Physicians may request coverage of these products using the Prescription Drug Medication Request Form, which can be accessed online in Highmark's Provider Resource Center. Under **Forms**, select **Miscellaneous Forms**, and select the form titled **Request for Non-Formulary Drug Coverage**.

C. Additions to the Specialty Tier

(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name
Vumerity	diroximel fumarate
Ibrance tablets	palbociclib

Talicia	omeprazole/amoxicillin/rifabutin
Ziextenzo	pegfilgrastim-bmez
Reblozyl	luspatercept-aamt
Fetroja	cefiderocol
Brukinsa	zanubrutinib
Adakveo	crizanlizumab-tmca
Abrilada	adalimumab-afzb
Givlaari	givosiran
Exservan oral film	riluzole
Oxbryta	voxelotor
Avsola	infliximab-axxq
Vyondys 53	golodirsen
Padcev	enfortumab vedotin-efjv
Enhertu	fam-trastuzumab deruxtecan-nxki
Caplyta	lumateperone
Ayvakit	avapritinib

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Adakveo (crizanlizumab-tmca) – Medicare	MedD	New policy created for Adakveo (crizanlizumab-tmca) to ensure that the member is 16 years of age or older with sickle cell disease with a history of at least 1 vasoocclusive crisis (VOC) and tried and failed hydroxyurea or is concurrently using with hydoxyurea. Reauthorization criteria attesting stability of VOC(s) or decrease in number of VOC(s).
Adalimumab BIOSIMILARS – Medicare	MedD	Policy revised to include Abrilada (adalimumab-afzb). Policy revised to include exception criteria for members that may require initial biologic therapy for juvenile idiopathic arthritis and to step through two immunosuppressants to one corticosteroid for severe ulcerative colitis. The policy split out the recommended age group for each diagnosis.
Androgen Receptor Inhibitors – Medicare	MedD	Policy revised to include expanded FDA-approved indication for Xtandi (enzalutamide) in metastatic castration-sensitive prostate cancer.
Atypical Antipsychotics – Medicare	MedD	Policy revised to include Caplyta (lumateperone) and ensure appropriate use in adult members with schizophrenia.
Bruton's Tyrosine Kinase Inhibitors – Medicare	3/1/2020	Policy revised to add criteria for FDA-approved Brukinsa (zanubrutinib) in adults with mantle cell lymphoma who have received at least one prior therapy; and for the FDA-approved expanded indication for Calquence (acalabrutinib) in adults with CLL or SLL.
Conjupri (levamlodipine) – Medicare	Best Date	New policy created to ensure appropriate use in members with a diagnosis of hypertension who have experienced therapeutic

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		failure, contraindication, or intolerance to two of the following: amlodipine, felodipine, nifedipine extended-release
Etanercept BIOSIMILARS – Medicare	MedD	Policy revised to include Eticovo (etanercept-ykro) and expanded indications of psoriatic arthritis and plaque psoriasis for Erelzi (etanercept-szzs). Policy revised to include exception criteria for members that may require initial biologic therapy for juvenile idiopathic arthritis. The policy split out the recommended age group for each diagnosis.
Chronic Inflammatory Diseases – Medicare	2/5/2020	Policy revised to include Xeljanz XR (tofacitinib XR) as preferred agent for ulcerative colitis.
Exondys 51 (eteplirsen) – Medicare	MedD	Policy revised to remove criteria requiring Exondys 51 (eteplirsen) to be prescribed by a physician who specializes in the treatment of muscular dystrophy and to remove criteria requiring the member to be ambulatory.
Exservan and Tiglutik (riluzole) – Medicare	MedD	Policy revised to include the newly FDA-approved Exservan (oral-film formulation of riluzole) for members with a diagnosis of amyotrophic lateral sclerosis (ALS) who have an inability to swallow tablets.
Givlaari (givosiran) – Medicare	MedD	New policy created to ensure appropriate use in adults with acute hepatic porphyria (AHP)
Hepatitis C Oral Agents – Medicare	MedD	Policy revised to align with the most recent AASLD/IDSA guidelines.
Infliximab BIOSIMILARS – Medicare	MedD	Policy revised to include newly FDA-approved biosimilar: Avsola (infliximab-axxq).
Interleukin (IL)-5 Antagonists – Medicare	MedD	Policy revised to add quantity limit for initial induction dose.
Intraocular Pressure Reduction Agents – Medicare	MedD	Policy created to combine Vyzulta (latanoprostene bunod), Rhopressa (netarsudil), and Rocklatan (netarsudil/latanoprost) policies. Member must have diagnosis of open-angle glaucoma or ocular hypertension, step through latanoprost and one additional medication from the following classes: prostaglandin analogs, beta blockers, alpha-adrenergic agonists, carbonic anhydrase inhibitors, cholinergic agonists or combination products of the above classes.
Mayzent (siponimod) – Medicare	2/5/2020	Policy revised to remove reauthorization criteria and update authorization duration to be 24 months.
Non-Stimulant Treatment of ADHD/ADD – Medicare	MedD	Policy revised to remove specific contraindications from approval criteria and move to background.
Nourianz (istradefylline) – Medicare	2/1/2020	Policy revised from requiring therapeutic failure, contraindication, or intolerance to selegiline and entacapone to requiring therapeutic failure, contraindication, or intolerance to two of the following agents: selegiline, rasagiline, pramipexole or pramipexole ER, ropinirole or ropinirole ER, or entacapone.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Ofev (nintedanib) and Esbriet (pirfenidone) – Medicare	MedD	Policy revised to ensure that members have documentation of a high resolution CT scan demonstrating ≥10% pulmonary fibrosis.
Oxbryta (voxelotor) – Medicare	3/1/2020	New policy created for Oxbryta (voxelotor) to ensure that the member is 12 years of age or older with sickle cell disease.
PARP Kinase Inhibitors – Medicare	MedD	Policy revised to provide expanded FDA-approved indication criteria for Lynparza (olaparib) in pancreatic adenocarcinoma.
PDGFR Tyrosine Kinase Inhibitors – Medicare	MedD	New policy created for Ayvakit (avapritinib) to ensure members are 18 years of age or older with a diagnosis of unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation.
Programmed Death Receptor Therapies – Medicare	MedD	Policy revised with expanded FDA-approved indication for Keytruda (pembrolizumab) in non-muscle invasive bladder cancer.
Pulmonary Hypertension – Medicare 2020	TBD	Policy revised for pulmonary hypertension agents to clarify that NYHA or WHO functional class symptoms are from baseline and removal of reasoning why member is using the agent as diagnosis is already required. Applies to all targeted agents.
Reblozyl (luspatercept-aamt) – Medicare	MedD	New policy created to ensure appropriate use in adults with beta thalassemia who require regular (red blood cell) RBC transfusions.
Sublingual Immunotherapies – Medicare	MedD	Policy revised to extend the indication for Oralair (sweet vernal, orchard, perennial rye, timothy and Kentucky blue grass mixed pollens allergens extract) for use in members five to nine years of age.
Targretin (bexarotene) – Medicare	MedD	Policy revised to revise criteria for Targretin (bexarotene) to align with FDA-approved indication of disease refractory to at least one systemic therapy.
Tecentriq (atezolizumab) – Medicare	MedD	Policy revised for Tecentriq (atezolizumab) to include expanded FDA-approved indication for first-line treatment of extensive-stage small cell lung cancer in combination with carboplatin and etoposide; and to clarify existing criteria for disease progression in urothelial carcinoma, to reflect FDA-approved indication.
Tecfidera (dimethyl fumarate) and Vumerity (diroximel fumarate) – Medicare	3/1/2020	Policy revised to include Vumerity (diroximel fumarate) with requirement of diagnosis of a relapsing form of multiple sclerosis.
Topical Retinoid Therapy – Medicare	2/1/2020	Policy revised to add new topical retinoid product Aklief (trifarotene).
Vyondys 53 (golodirsen) – Medicare	Best Date	New policy created to ensure appropriate use in members with a diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation of the DMD gene that is amenable to exon 53 skipping who have been on a stable dose of oral corticosteroids for at least six months prior to initiating therapy.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Xcopri (cenobamate) – Medicare	MedD	New policy created for Xcopri (cenobamate) to require diagnosis of partial-onset seizures and trial of one other anti-epileptic drug.

*All effective dates are tentative and subject to delay pending internal review or approval.

2. Managed Prescription Drug Coverage (MRxC) Program *

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria
Vyzulta (latanoprostene bunod) – Medicare	MedD	Policy terminated.

*Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria.

3. Quantity Level Limit (QLL) Program*

(Effective date pending CMS approval, completion of internal review and implementation, unless otherwise noted.)

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Abrilada (adalimumab-afzb)	2 syringes or pens	6 syringes or pens
amphetamine	450 ml per 30 days	1350 ml
Ayvakit (avapritinib)	1 tablet per day	1 tablet per day
Brukinsa (zanubrutinib)	4 capsules per day	4 capsules per day
Caplyta (lumateperone)	1 tablet per day	1 tablet per day
Cequa (cyclosporine)	60 droperettes per 30 days	180 droperettes
Conjupri (levamlodipine)	1 tablet per day	1 tablet per day
Dayvigo (lemborexant)	1 tablet per day	1 tablet per day
Drizalma Sprinkle (duloxetine) 40mg	31 capsules	90 capsules
Drizalma Sprinkle (duloxetine) 30mg, 60 mg	62 capsules	180 capsules
Drizalma Sprinkle (duloxetine) 20mg	93 capsules	270 capsules
Duaklir Pressair (aclidinium/formoterol)	1 inhaler per 30 days	3 inhalers
Eucrisa (crisaborole)	1 tube per 28 days	3 tubes per 84 days
everolimus	31 tablets	90 tablets
Exservan (riluzole) oral film	1 carton (60 oral film pouches)	3 cartons (90 oral film pouches)
Ibrance (palbociclib) tablets	21 tablets per 21 days	21 tablets per 21 days
Nayzilam (midazolam)	10 nasal spray units per 30 days	30 nasal spray units
Olumiant (baricitinib)	31 tablets	90 tablets
Oxbryta (voxelotor)	3 capsules per day	3 capsules per day
Oxervate (cenegermin-bkbj)	112 drops per 56 days	112 drops per 56 days
Tosymra (sumatriptan)	12 doses per 28 days	36 doses per 84 days
Ubrelvy (ubrogepant)	16 tablets	48 tablets

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Valtoco (diazepam) nasal spray	2 cartons per dispensing event	2 cartons per dispensing event
Vumerity (diroximel fumarate)	4 capsules per day	4 capsules per day
Vyndamax (tafamidis)	31 capsules	90 capsules
Xenleta (lefamulin)	10 tablets per 180 days	10 tablets per 180 days

All effective dates are tentative and subject to delay, pending CMS approval, internal review, and implementation.